

Appl. No. 10/051,952  
Reply to Office Action of May 28, 2004

Remarks

Introduction

The above-identified application has been carefully reviewed in light of the Office Action mailed May 28, 2004, which included a final rejection of the pending claims, and the September 16, 2004 Advisory Action. A response to the Office Action was filed on August 28, 2004. The Advisory Action indicates that the response filed on August 28, 2004 was not entered.

Thus, Applicant is submitting this response, which includes the amendments to the claims and remarks of the August 28, 2004 response. Claims 1-4, 6-7, 9-10, 12, and 36-44 were pending. By way of this response, claim 4 has been amended, and claim 45 has been added. Support for the amendments to the claim can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1-4, 6-7, 9-10, 12, and 36-45 remain pending.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 has been amended by deleting the phrase "preferably solid or metallic material".

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In view of the above, applicant submits that the present claims, and in particular claim 4, satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1, 2, 6, 7, 9, 10, 12, 36, 37, and 40-44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic (U.S. Patent No. 5,183,462) taken with Vadoud-Seyedi et al. (hereinafter Vadoud). Claims 3, 4, 38, and 39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic in view of Vadoud, and further in view of McCabe (U.S. Patent No. 5,525,510).

The Examiner states that it would be obvious to a person of ordinary skill in the art to combine Borodic and Vadoud to treat wrinkles and brow furrows because Vadoud indicates the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, thus the injection of botulinum toxin with a Dermojet is an effective and comfortable technique.

Applicant traverses the rejections.

Applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of Borodic and Vadoud, and thus, the present claims are unobvious and patentable over the combination of Borodic and Vadoud under 35 U.S.C. § 103.

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Vadoud discloses needleless injection of a botulinum toxin into the sole of a patient's foot to treat plantar hyperhydrosis. As understood by persons of ordinary skill in the art, plantar hyperhydrosis is a condition involving excessive secretions from plantar sweat glands. Sweat glands are located in the dermal layer of the skin (e.g., see Exhibit A of the August 28, 2004 response, and page 22, line 32 of the specification of the above-identified application). Sweat glands are innervated by the sympathetic nervous system, a subset of the autonomic nervous system. Vadoud does not disclose, teach, or even suggest the use of a botulinum toxin to treat wrinkles or brow furrows.

Borodic discloses administration of a botulinum toxin by way of injection using a syringe with a needle. Borodic does not disclose, teach, or even suggest the use of a needleless syringe to deliver a botulinum toxin for any purpose, let alone to treat wrinkles and brow furrows.

The present claims are directed to methods of treating wrinkles and brow furrows by the needleless administration of a botulinum toxin. The wrinkles and brow furrows are treated by reducing a muscle contraction. Thus, the present claims are directed to the needleless administration of a botulinum toxin to treat wrinkles and brow furrows by interfering with the neuronal influence on a muscle. Claim 45 specifically states that the amount of botulinum toxin is administered to a subdermal muscle tissue in proximity to the wrinkle.

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Applicant submits that a person of ordinary skill in the art would not be motivated to combine Borodic and Vadoud, as proposed by the Examiner, because Vadoud only discloses the use of a botulinum toxin to interfere with the sympathetic nervous system. In particular, Vadoud only discloses needleless administration of a botulinum toxin to interfere with a neuronal influence on a sweat gland located in the dermal layer of the skin.

Vadoud does not disclose, teach, or suggest using needleless administration of a botulinum toxin to interfere with neuronal influence on a muscle, or to reduce a muscle contraction to treat wrinkles or brow furrows, as recited in the present claims. For example, Vadoud does not disclose, teach, or even suggest administration of a botulinum toxin to a subdermal tissue, such as a subdermal muscle tissue, as recited in claim 45. As understood by persons of ordinary skill in the art, muscle contractions are due to activity of the somatic nervous system. The somatic nervous system and the autonomic nervous system are structurally and functionally completely different and distinct, one from the other. For example, as discussed above, the sweat glands are located in the dermis of a human's skin. In contrast, muscle tissue is located below the skin, and in particular, below the dermis of the skin. Thus, the neuronal input is different for sweat glands and muscle.

Vadoud's teaching of needleless administration of a botulinum toxin to affect the sympathetic nervous system (i.e., a portion of the autonomic nervous system) does not provide any motivation or suggestion to a person of ordinary skill in the art to employ needleless administration of a botulinum toxin to

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affect the somatic nervous system, let alone to affect the somatic nervous system to treat a wrinkle or brow furrow by reducing a muscle contraction, as recited in the present claims.

Moreover, applicant submits that Vadoud actually teaches away from using a needleless injection of botulinum toxin to treat wrinkles or brow furrows by reducing a muscle contraction, as recited in the present claims, such as by administering an amount of botulinum toxin to a subdermal muscle tissue, as recited in claim 45. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)). As discussed herein, Vadoud's teaching of needleless administration of botulinum toxin to interfere with a neuro-glandular communication does not even suggest that such administration would be effective to interfere with a neuro-muscular communication, let alone to do so and treat wrinkles or brow furrows by reducing a muscle contraction. Thus, applicant submits that the limited teachings of Vadoud with respect to needleless administration of botulinum toxin, that is limited to treating plantar hyperhydrosis, actually teaches away from and certainly provides no motivation or incentive to a person of ordinary skill in the art to treat wrinkles or brow furrows with a botulinum toxin using a needleless syringe. Further, Borodic does not supply the deficiencies apparent in the teachings of Vadoud.

In addition, and as the Examiner has acknowledged, treatment of wrinkles and brow furrows is different and distinct from treatment of other conditions. In particular, the Examiner has stated that wrinkles and brow furrows are distinct from

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other conditions or diseases because "the diagnosis and treatment of each disease are different, and the treatment of each disease has a different outcome." (see September 16, 2003 Office Action, page 3, lines 1-2). Thus, applicant submits that because treatment of wrinkles and brow furrows is distinct from treatment of hyperhydrosis, a person of ordinary skill in the art would not be motivated to combine Borodic and Vadoud.

In view of the above, applicant submits that the present claims, and in particular claims 1, 2, 6, 7, 9, 10, 12, 36, 37, and 40-45 are unobvious from and patentable over Borodic in view of Vadoud under 35 U.S.C. § 103. In addition, applicant submits that claims 3, 4, 38, and 39 are similarly unobvious from and patentable over the combination of Borodic in view of Vadoud and further in view of McCabe since a person of ordinary skill in the art would not be motivated to combine Borodic with Vadoud.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

#### Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant

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submits that the present claims, that is claims 1-4, 6-7, 9-10, 12, and 36-45 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: \_\_\_\_\_

9/27/04

Respectfully submitted,



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